REMARKS

I. Claim Amendments

Claim 1 has been amended to recite that the composition containing benzyl alcohol is administrated at a dose of 1mg-50mg/tumor volume (cm^3), wherein the dose is sufficient to cause cells of the tumor to become necrotic. Support for this amendment can be found in original claim 15.

Claim 1 has also been amended to recite that the tumor comprises stomach, breast, large bowel, thyroid gland or pancreatic tumor cells, as supported by original claim 5.

Claims 4, 6, and 7 have been amended by deleting the recitation of vitamin C.

Claims 16 and 17 have both been amended to depend from any one of claims 1 to 7.

Claims 2 and 6 have been amended to correct "external" to "externally." In addition, minor amendments have also been made to claim 16 to delete redundant limitations and otherwise clarify the claim language. These amendments to claims 2, 6, and 16 are grammatical and editorial in nature and do not affect the scope of the claims.

Claims 5 and 8-15 have been canceled.

No new matter has been added, and Applicants respectfully request entry of these amendments to the claims.

After entry of this amendment, claims 1-4, 6, 7, 16, and 17 will be pending in the application.

II. Response to Claim Rejections Under 35 U.S.C. § 102

A. Bessette (WO 00/33857)

At page 2 of the Office Action, claims 1-3, 5, 8, and 9 were rejected under 35 U.S.C. § 102(b) as being anticipated by Bessette (WO 00/33,857).

Specifically, it was asserted that Bessette teaches a pharmaceutical composition for the treatment of soft tissue cancer in mammals comprising at least one plant essential oil. It was also stated that the reference includes a specific embodiment where the plant oil is benzyl alcohol. In addition, it was stated that the reference specifically teaches treatment of human breast cancer cells (MCF-7) with 50 μg/ml benzyl alcohol.

As noted above, claim 1 has been amended to recite that the composition containing benzyl alcohol is administrated at a dose of 1mg-50mg/tumor volume (cm^3), wherein the dose is sufficient to cause cells of the tumor to become necrotic. In contrast, the experimental results described in Bessette indicate that benzyl alcohol's (BA's) antitumor effect on breast cancer cells is caused by "protection against the E2-induced abnormal growth in cancer breast cells." The experimental system used in Bessette does not use the death rate of cancer cells as a marker. Further, Bessette does not teach or suggest that BA administration causes tumor cells to become necrotic.

In fact, Fig. 1 of the Certified Experimental Result 1, shown in the Declaration of Dr. Takeyama submitted herewith, demonstrates that BA administrated at the concentration described in Bessette does not cause changes in adhesive property or cell death. Specifically, BA was administrated at a concentration of 50μg/ml, as described in Example 3 of Bessette. The

results in the Declaration show that administration at a concentration of 50μg/ml does not cause tumor cells to become necrotic. Therefore, Bessette does not teach or suggest that BA administration at the concentration recited in the present claims induces necrosis in cancer cells.

In view of the above, Applicants respectfully request reconsideration and withdrawal of this rejection.

B. References PP-1457 and B-323

At pages 3 and 4 of the Office Action, claims 1-3, 5, 8, and 9 were rejected under 35 U.S.C. § 102(b) as being anticipated by "The antitumor effect to stomach cancer by benzyl alcohol," Meeting of Japan Surgical Society on April 12-14, 2000, issued on March 10, 2000, PP-1457, hereafter referred to as "Reference PP-1457;" and by "The antitumor effect of benzyl alcohol against breast cancer," The 10th Annual Meeting of the Japanese Breast Cancer Society, July 5-6, 2002, B-323, hereafter referred to as "Reference B-323."

According to the Office Action, the references teach that benzyl alcohol induces apoptosis in stomach cancer cells (PP-1457) and breast cancer cells (B-323).

Both PP-1457 and B-323 disclose that administration of BA at concentrations of 300μg-1000μg has an antitumor effect on stomach cancer or breast cancer. However, administration of BA at concentrations of 300μg-1000μg is not sufficient to induce tumor cell death (see Fig. 1 in the enclosed Declaration).

In addition, PP-1457 discloses that death of stomach cancer cells is caused by apoptosis rather than necrosis. Similarly, B-323 discloses that death of MCF-7 (a breast cancer cell line)

cells is caused by apoptosis rather than necrosis, and that the reason for BSMZ (another breast cancer cell line) cell death is not known.

Therefore, neither PP-1457 nor B-323 teach or suggest that BA administration at the concentration recited in the present claims induces necrosis in cancer cells.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

III. Response to Claim Rejections Under 35 U.S.C. § 103

At page 5 of the Office Action, claims 1-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Smorenburg, et al. (2001) Pharmacological Reviews, 53(1):93-105 (Smorenburg), in view of Bessette, and in light of Stedman's Medical Dictionary, 25th Edition (1990), 1026-1027.

Specifically, it was contended that Smorenberg teaches heparins as anti-cancer drugs. The Examiner relies on Bessette (discussed above) for the description of benzyl alcohol. The Examiner concluded that it would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine heparin and BA, as the prior art shows that each compound is useful for treating cancerous tumors.

The present inventors have discovered that administration of BA at the proper concentration can cause tumor cells to become necrotic. Applicants submit that the references cited by the Examiner do not teach or suggest tumor cell death by necrosis, nor the proper concentration of BA administration to cause tumor cell death by necrosis. Thus, a person of

ordinary skill in the art would not have been able to predict the methods recited in the present claims based on the cited references.

Further, Smorenberg merely teaches heparins as anti-cancer drugs, and does not teach or suggest combination therapy using BA with vitamin C. In addition, combination of the cited references does not teach or suggest combination therapy using BA with vitamin C.

Also, the Certified Experimental Result 2 (see the Declaration submitted herewith) shows that combination administration of BA with vitamin C can cause an antitumor effect at very low concentrations (BA: 39.1μg/ml, vitamin C: 391μg/ml refer to Result of attachment 2) compared with administration of BA alone. This result would not have been expected by a person of ordinary skill in the art at the time of the present invention.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the obviousness rejection.

IV. Response to Claim Rejections Under 35 U.S.C. § 112 First Paragraph

At page 7 of the Office Action, claims 1-17 were rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement.

Specifically, it was asserted that the specification enables methods of treating stomach tumor cells, breast tumor cells, large bowel tumor cells, thyroid gland tumor cells, and pancreatic tumor cells with benzyl alcohol.

However, it was contended that the specification does not enable treating all types of cancer cells or all types of tumor growth in vivo; treating tumor cells for any cancer types other

than stomach, breast, large bowel, thyroid gland, and pancreatic tumor cells using benzyl alcohol; or combination therapy of benzyl alcohol with heparin or vitamin C.

As noted above, Applicants have amended claim 1 to recite that the tumor comprises "stomach, breast, large bowel, thyroid gland or pancreatic tumor cells." Applicants submit that the present specification enables treatment of the recited tumors.

Further, as shown in Experimental Result 2 in the Declaration submitted herewith, the specification also enables combination therapy using BA with vitamin C.

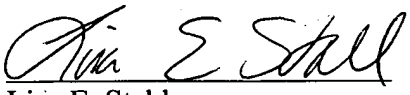
Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

V. Conclusion

In view of the above, reconsideration and allowance of claims 1-4, 6, 7, 16, and 17 of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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